Group of New England from January 2010 to June 2012. Kaplan-Meier analysis evaluated relationships between gender and primary outcomes of major amputation and overall survival at 1 year.

Results: Indications for PVI included IC in 719 (22%) vs 1173 (35%) and CLI in 597 (18%) vs 849 (25%), women and men, respectively. Women were older (69 vs 66 mean years, $P < .00001$) with less diabetes (43% vs 49%, $P = .01$), renal insufficiency (4.6% vs 7.3%, $P = .0029$), coronary artery disease (28% vs 35%, $P < .00001$), smoking (76% vs 86%, $P = .01$), and statin use (60% vs 64%, $P = .0058$). Women were more likely to present with CLI (45% vs 42%, $P = .0028$) and ambulate with assistance (16% vs 12%, $P = .0016$). Technical success (95% vs 94%, $P = .11$), vascular injury (1.3% vs 1.0%, $P = .82$), and embolization (1.6% vs 1.3%, $P = .46$) were similar, with higher rates of hematoma (7.1% vs 3.4%, $P < .0001$) and access-site occlusion (0.91% vs 0.24%, $P = .0085$) in women. There were no differences in 1-year major amputation rates between men and women for patients with IC or CLI. Survival at 1 year was similar between women and men with IC (95% vs 96%, $P = .19$) and CLI (77% vs 79%, $P = .35$). The model demonstrated moderate discriminative ability (receiver-operating characteristic curve, 0.81; Fig, Table).

Conclusions: Procedural morbidity was modestly greater in women, with higher rates of hematoma and access-site occlusion. We found no gender disparity in amputation rates or overall survival in patients undergoing PVIs for claudication or CLI. Further study is necessary to determine if gender should play a role in selection of therapy for patients harboring lower extremity occlusive disease.

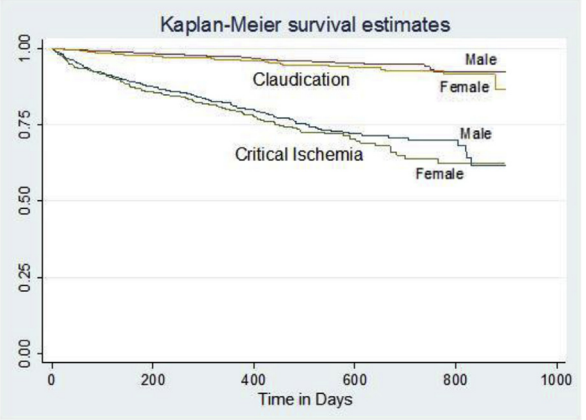

Fig. Kaplan-Meier survival estimates.

Table. Predictors of overall survival after peripheral vascular intervention

Variable	*OR*	*95% CI*	P
Age	1.04	1.02-1.06	.0001
Claudication	0.41	0.30-0.57	.0001
Congestive heart failure	2.32	1.70-3.18	.0001
COPD	1.57	1.15-2.13	.004
Nonambulatory pre-op	2.83	1.57-5.10	.001
β-Blocker use	1.42	1.03-1.96	.034

CI, Confidence interval; *COPD*, chronic obstructive pulmonary disease; *OR*, odds ratio.

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Differential Effect of Atherosclerotic Risk Factors on Vascular Disease Phenotypes Between the Sexes◇

Caron B. Rockman, Yu Guo, Glenn R. Jacobowitz, Thomas Maldonado, Neal Cayne, Firas Mussa, Mark Adelman, Jeffrey Berger. New York University Medical Center, New York, NY

Objectives: Most reported studies on atherosclerosis involve a predominance of men. There is a lack of information into the specific role of atherosclerotic risk factors and their effects on the development of peripheral vascular diseases in women. The goal of this study was to analyze the association of known risk factors and the prevalence peripheral arterial disease (PAD), carotid stenosis (CS), and abdominal aortic aneurysm (AAA) in men and women.

Methods: Data of 3,696,778 individuals who underwent vascular screening examinations were used. PAD was defined as an ankle-brachial index of ≤0.9, CS as stenosis of ≥50% of the left or right internal carotid artery, and AAA as an aortic diameter of ≥3 cm. Multivariate analyses were used to determine odds ratios for the effect of each individual risk factor on each phenotype of vascular disease in men and women.

Results: Overall, AAA was noted in 1.8% of men (n = 1,392,169) and in 0.3% of women (n = 2,304,609). Respective rates of PAD and CS were 3.2% and 4.4% in men, and 3.8% and 3.5% in women. Odds ratios for the association of risk factors with vascular disease phenotypes in men and women are reported in the Table. Increased age and a positive smoking history were more significantly associated with AAA in men than in women, and diabetes was mildly protective against AAA in men but not in women. Increased age was more significantly associated with CS in men than in women, whereas hypertension, diabetes, and a positive smoking history were more significant risk factors in women. Increased age, a positive smoking history, and diabetes were more significant risk factors for PAD in men; obesity (body mass index >30 kg/m^2) conferred a mildly protective association with PAD in men but was a positive risk factor for the prevalence of PAD in women.

Conclusions: Our study suggests that atherosclerotic risk factors may not have the same effects on vascular diseases in men and women. Increased age appears to be a more significant risk factor in men. Notably, diabetes was inversely associated with AAA in men but not in women, and obesity was mildly protective against PAD in men but not in women. Our results suggest that atherosclerotic risk factor reduction strategies may need to be sex-specific.

Table. Odds ratios for the association of risk factors with phenotypes of vascular disease in men and women

Risk factor	*Age > 70 years*	*Hypertension*	*Hyperlipidemia*	*+Smoking history*	*Diabetes*	*Obesity (BMI >30 kg/m^2)*
AAA						
Men	3.08	1.44	1.47	2.39	0.94	NS on univariate analysis
Women	1.95	1.28	1.27	1.65	1.19	NS on univariate analysis
CS						
Men	2.79	1.87	1.66	1.67	1.55	NS on univariate analysis
Women	2.30	1.99	1.60	1.79	1.64	NS on univariate analysis
PAD						
Men	2.61	1.75	1.16	1.95	1.73	0.84
Women	2.27	1.62	1.08	1.70	1.52	1.10

AAA, Abdominal aortic aneurysm; *BMI*, body mass index; *CS*, carotid stenosis; *NS*, not significant; *PAD*, peripheral arterial disease.

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Current Outcomes of Lower Extremity Bypass in High-Risk Patients†

Julia T. Saraidaridis,[1] Emel Ergul,[1] Virendra I. Patel,[1] David H. Stone,[2] Richard P. Cambria,[1] Mark F. Conrad[1]. [1]Massachusetts General Hospital, Boston, Mass; [2]Dartmouth-Hitchcock Medical Center, Lebanon, NH

Objectives: In 2009, the Society for Vascular Surgery established objective performance goals (OPG) for lower extremity bypass (LEB) in patients with critical limb ischemia (CLI) based on pooled data from previously performed prospective studies. Patients with a prosthetic conduit and end-stage renal disease (ESRD) were excluded. Patients within the

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OPG cohort were stratified into low-risk and high-risk groups based on age, distal target, poor conduit quality, and procedures performed for tissue loss. However, in the era of endovascular revascularization, few patients who undergo LEB fall into the low-risk OPG category. Therefore, the goal of this study was to determine safety and efficacy measures for those patients who do not fall into the OPG cohort.

Methods: All patients who underwent LEB for CLI in the Vascular Study Group of New England database from 2003 to 2013 were identified. Patients were stratified by OPG criteria into OPG and non-OPG cohorts, and the OPG cohort was divided into high-risk and low-risk strata. Outcomes included 30-day major adverse limb event, 30-day major adverse cardiac event (MACE), 1-year survival, 1-year limb salvage, and 1-year primary patency rates.

Results: We identified 4190 patients: 2649 (63%) OPG and 1541 (37%) non-OPG. Of the OPG cohort, 2506 (95%) were high risk, 143 (5%) were low risk. A total of 1467 (35%) had a previous bypass (43% non-OPG, 30% OPG; $P < .001$). The 30-day major adverse limb event was 5.6% (6% non-OPG, 5.4% OPG; $P = .36$), and the MACE was 8.3% (10.3% non-OPG, 7.1% OPG; $P < .001$). At 1 year, limb salvage was 85% (77% non-OPG, 89% OPG; $P < .001$), survival was 83% (75% non-OPG, 87% OPG; $P < .001$), and primary patency was 70% (72% OPG, 66% non-OPG; $P = .009$).

Conclusions: In contemporary practice, 97% of patients undergoing LEB for CLI would be excluded or considered high risk based on the Society for Vascular Surgery OPG criteria and therefore cannot be held to this standard. For the non-OPG group, the 30-day MACE of 10.3%, 1-year limb salvage of 77%, and 1-year survival of 75% are lower than OPG metrics but are more realistic in this high-risk cohort of patients.

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One-Year Outcomes From an International Multicenter Study of Zenith TX2 Low Profile Endovascular Graft for Thoracic Endovascular Repair◇

Karl A. Illig,[1] Takao Ohki,[2] Chad Hughes,[3] Masaaki Kato,[4] Hideyuki Shimizu,[5] Shraddha Mehta[6]. [1]University of South Florida, Tampa, Fla; [2]Jikei University Hospital, Tokyo, Japan; [3]Duke University, Durham, NC; [4]Morinomiya Hospital, Osaka, Japan; [5]Keio University Hospital, Tokyo, Japan; [6]MED Institute, West Lafayette, Ind

Objectives: We evaluated the safety and effectiveness of the Zenith TX2 Low Profile Endovascular Graft for the treatment of descending thoracic aortic aneurysms and large ulcers.

Methods: The Zenith TX2 Low Profile Endovascular Graft, with a 16F to 20F delivery system, was developed to address vascular access issues associated with larger-profile devices and to increase conformability in tortuous anatomy. This prospective, nonrandomized, multicenter study was conducted in Europe, Japan, and the United States. Main anatomical inclusion criteria included proximal neck of ≥20 mm, aortic arch radius of ≥20 mm, and a neck diameter of 15 to 42 mm. Patients were evaluated preprocedure, predischarge, at 1, 6, and 12 months, and yearly thereafter through 5 years. One-year results as of December 2, 2013, are presented.

Results: Between March 2010 and January 2013, 110 patients (mean age, 72 ± 10 years) were treated with the TX2 Low Profile device for descending thoracic aortic aneurysms (n = 90) or ulcers (n = 20). Women constituted 42% (46 of 110) of the study population. Percutaneous access was performed in 31% (34 of 110). The study device was successfully implanted in all but two patients (both failure of delivery due to severe iliac calcification). There was no 30-day mortality. Three deaths occurred ≤1 year; none were judged aneurysm-related or repair-related by independent adjudication. One-year morbidity included stroke in five patients (2 procedure-related by independent adjudication) and renal failure in two patients (both with a preoperative history of chronic kidney disease). Secondary endovascular intervention was performed in two patients, one for type II endoleak and one for proximal dissection. No conversions, rupture, Q-wave myocardial infarction, or paraplegia was observed ≤1 year.

Conclusions: Early outcomes appear promising and suggest expanded thoracic endovascular aortic repair applicability with increased female population and percutaneous access. Longer-term follow-up is ongoing.

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Routine Use of Ultrasound Guidance in Femoral Arterial Access for Peripheral Vascular Intervention Decreases Groin Hematoma Rates†

Jeffrey Kalish,[1] Mohammad Eslami,[1] David Gillespie,[2] Marc Schermerhorn,[3] Denis Rybin,[4] Gheorghe Doros,[4] Alik Farber[1]. [1]Boston Medical Center, Boston, Mass; [2]Southcoast Health System, Fall River, Mass; [3]Beth Israel Deaconess Medical Center, Boston, Mass; [4]Boston University School of Public Health, Boston, Mass

Objectives: Use of fluoroscopy and bony landmarks to guide percutaneous common femoral artery (CFA) access has decreased access site complications compared with palpation alone. However, only limited case series have examined the benefits of ultrasound imaging to guide CFA access during peripheral vascular intervention (PVI). We evaluated the effect of routine vs selective use of UG on groin hematoma rates after PVI.

Methods: The Vascular Study Group of New England database (2010-2014) was queried to identify the complication of postprocedural groin hematoma after 7359 PVIs performed by CFA access. Hematoma (including pseudoaneurysms) was defined as minor (requiring compression or observation), moderate (requiring transfusion or thrombin injection), and major (requiring operation). Multivariable Poisson regression models were used to compare hematoma rates of surgeons based on routine (≥80% PVI) and selective (<80%) use of UG in the adjusted overall sample and in multiple subgroups.

Results: The overall groin hematoma rate after PVI was 4.5%, and the rate of combined moderate and major hematoma was 0.8%. Among 114 surgeons with ≥10 PVI procedures, 31 surgeons (27%) used UG routinely and 83 (73%) used UG selectively. Routine UG was protective against hematoma (rate ratio [RR], 0.74; 95% confidence interval [CI], 0.57-0.95; $P = .02$). Subgroup analysis revealed that routine UG was also protective against hematoma under the following circumstances: age >80 years (RR, 0.47; 95% CI, 0.26-0.85; $P = .01$), body mass index ≥30 kg/m^2 (RR, 0.51; 95% CI, 0.29-0.90; $P = .02$), timing of procedure in the first half of the academic year (RR, 0.56; 95% CI, 0.38-0.82; $P < .01$), and sheath size >6F (RR, 0.43; 95% CI, 0.23-0.79; $P < .01$).

Conclusions: Routine UG may potentially protect against the complication of hematoma for modifiable and nonmodifiable patient/procedural characteristics. Encouraging routine UG is a feasible quality improvement opportunity to decrease patient morbidity after PVI.

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The Role of T Cells in Resolution of Deep Venous Thrombosis In Vivo◇

Suzanne Siefert, Joel Gabre, Christine Chabasse, Mark Hoofnagle, Rajabrata Sarkar. University of Maryland, Baltimore, Md

Objectives: T cells regulate adaptive immunity and a number of forms of vascular remodeling, but their role in venous thrombus resolution remains undefined. Our objective was to define the presence and function of T cells during resolution of deep venous thrombosis in vivo.

Methods: Thrombus resolution was studied in CD-1 mice after inducing stasis deep venous thrombosis by vena caval ligation. Inflammatory cell subtypes were characterized by immunohistochemistry and flow cytometry of thrombi at various time points. The role of T cells in mediating thrombus resolution was defined by T-cell depletion with anti-CD-3 or control antibody treatment and by thrombus resolution assessed by thrombus + vein wall weight at day 12. Gene expression after T cell depletion was studied by Western blotting and zymography of thrombi.

Results: Immunocytochemistry of thrombus and vein wall sections did not consistently demonstrate the presence of T cells during thrombus resolution (days 2 to 12) but did show typical patterns of neutrophil and then macrophage infiltration. Flow cytometry of cell suspensions from thrombi identified 2.93% of cells as CD3$^+$ T cells at day 8, with a peak of 48% CD3$^+$ T cells and 10% B cells at day 8. Immunosubtyping revealed regulatory CD4 T cells (40%) and cytotoxic CD8 T cells (30%) on day 8. T-cell depletion with anti-CD3 antibody treatment during thrombus resolution (days 0 to 12) reduced spleen T-cell counts by

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